K132401

Section 6: 510(k) Summary

APR 0 9 2014

Applicant/ Manufacturer: Karin Breding
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Date prepared: 2014-04-07

Proprietary Name: MEGA ISQ

Common Name: Dental implant stability analyzer

Classification Status: Class I

Product Codes: EKX - handpiece, direct drive, ac-powered

Predicate Device: Osstell ISQ (K082523)

Device Description:

The MEGA ISQ is an new generation of the Osstell ISQ, (K082523) the system is designed to measure dental implant stability in the oral cavity and maxillofacial region. Similar to K082523, the MEGA ISQ is a portable, handheld instrument that involves the use of the noninvasive technique, Resonance Frequency Analysis. The system involves the use of a Smartpeg (aluminum rod) attached to the dental implant by means of a screw. The Smartpeg is excited by a magnetic pulse from the measurement probe on the handheld instrument. The resonance frequency, which is the measure of implant stability, is calculated from the response signal. Results are displayed as the Implant Stability Quotient (ISQ). The ISQ is a measurement of the stability of the implant and is derived from the resonance frequency value obtained from the Smartpeg.

Indication for Use:
The MEGA ISQ is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.

Summary of Technological Characteristics:
The modifications to the Osstell ISQ since its previous clearance in K082523 include the following changes:

- Replacing the existing display with a LED display
- Removing the RAM memory
- Removing the real time clock
- Move the USB interface to a dock station
- A new material is added to the instrument and docking station to improve grip ability

These minor differences do not affect the safety or performance of the device and do not change the intended use of the MEGA ISQ. These changes were implemented to address the needs of the customer for a basic device which offers the same Resonance Frequency Analysis technology, but does not offer the capability of data storage. The relocation of the USB interface allows a reduce size, as well as allowing for a slightly larger display.

Summary of Nonclinical Testing:
Based on the Risk Analysis, the verification and validation tests that were performed and the acceptance criteria applied included:

- Conformance to EN IEC 60601-1-2
- Comparative performance testing to predicate
- Material biocompatibility
- Updated steam sterilization parameters in accordance with ANSI/AAMI/ST79:2010/A2:2011

The proposed device passed all applicable test per IEC 60601-1-2, comparative testing of the new LED display, performance of the USB interface, and performance and biocompatibility of the new material demonstrated equivalent performance to the declared predicate.

Clinical Studies:
Clinical data was not required to support the changes to the Osstell ISQ.

Substantial Equivalence Discussion:

The modified MEGA ISQ has the following similarities to the Osstell ISQ previously cleared in K082523:

- has the same indicated use,
- uses the same operating principle,
- incorporates the same basic device design and physical properties,
- has no change in autoclave or single use components, or device software

The modified MEGA ISQ has the following differences to the Osstell ISQ previously cleared in K082523:

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- Removes the RAM memory
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- A new material is added to the instrument and docking station to improve grip ability

	MEGA ISQ	Predicate Device: Osstell ISQ K082523
Indication for use	The MEGA ISQ is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.	No change in Indication for Use
Operation of System	The MEGA ISQ measures the frequency response from Smartpeg that is directly attached to the implant or abutment. The system includes the following components: Instrument, Smartpeg/Measurement Probe, and PC Data Manager Software. The technique involves a smartPeg (10 mm x 3 mm) that is attached to the implant or abutment. The SmartPeg is excited over a range of frequencies (1 kHz to 10 kHz) and the resonance frequency is measured with the MEGA ISQ instrument and software. The resonance frequency is determined by the stiffness of the implant system. The MEGA ISQ presents the resonance frequency as an Implant Stability Quotient (ISQ) value (scaled 0-100). The ISQ value is proportional to the stability of the implant.	No change in operation of system
System Components-	**Instrument** The Instrument is a portable , handheld instrument	**Instrument** The Instrument is a compact unit

	MEGA ISQ	Predicate Device: Osstell ISQ K082523
	with a built-in LED display. The unit operates from a rechargeable power source offering over 1.5 hours of continuous use between charges. The Measurement Probe, connected to the instrument, is held close to the Smartpeg. The measurement probe sends the excitation signal to the coil in the probe, and also detects the response signal from the second coil in the probe. The microcontroller in the instrument calculates the frequency of the response signal, and presents it on the display as a number, the Implant Stability Index (ISQ). The instrument can be connected to a PC via the USB cable and firmware can be updated. **Smartpeg/Measurement Probe** The stability of the implant is reflected by the resonance frequency of a "Smartpeg" attached to the implant. The Smartpeg is a small aluminum rod, approximately 3 mm in diameter and 10 mm long, with a magnet permanently attached to its top. The Smartpeg is screwed onto the implant. The Smartpeg magnet is excited by a small magnetic pulse generated by a coil in the measurement probe. The Smartpeg vibrates freely at its resonance frequency for some milliseconds. Since the magnet attached to its top is vibrating together with the Smartpeg, the vibration (the "ringing") can be picked up by a second coil in the measurement probe. **PC Data Manager Software** Data transfer is not an option for the MEGA ISQ.	with built-in graphical display. The unit operates from a rechargeable power source offering over 6 hours of continuous use between charges. The Measurement Probe, connected to the instrument, is held close to the Smartpeg. The measurement probe sends the excitation signal to the coil in the probe, and also detects the response signal from the second coil in the probe. The microcontroller in the instrument calculates the frequency of the response signal, and presents it on the display as a number, the Implant Stability Index (ISQ). Four hundred measurements may be stored in the instrument. The instrument can be connected to a PC via the USB cable and the measurement data can be transferred to the optional ISQ Data Manager Software. **Smartpeg/Measurement Probe** No change to Smartpeg or Measurement probe **PC Data Manager Software** The Osstell ISQ Data Manager is a Windows 2000/NT/XP/Vista based software enabling storage, viewing and printing of patient data. The Software is an optional accessory to the Osstell ISQ and is not integral to the functioning of the device.
Instrument and Docking Station materials	ABS Plastic and Dryflex TPE	ABS Plastic
Device Display	LED -58mm x 37mm	LCD – 64mm x 32mm

Conclusion:

The change to display, RAM memory, Clock ,USB interface, and additional device material of the MEGA ISQ do not change the intended use nor do they affect the safety and effectiveness as compared to the Osstell ISQ previously cleared in K082523. Therefore the MEGA ISQ can be found substantially equivalent to the Osstell ISQ cleared in K082523.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2014

Osstell AB
C/O Ms. Cherita James
Regulatory Consultant
M Squared Associates, Incorporated
901 King Street, Suite 101
Alexandria, VA 22314

Re: K132401
Trade/Device Name: MEGA ISQ
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: March 14, 2014
Received: March 18, 2014

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID
FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

Section 5: Indications for Use Statement

510(k) Number (if known): K132401

Device Name: MEGA ISQ

Indications For Use: The MEGA ISQ is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.

Prescription Use ___X____ AND/OR Over-The-Counter Use _______

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2014.04.07 14:17:46 -04'00